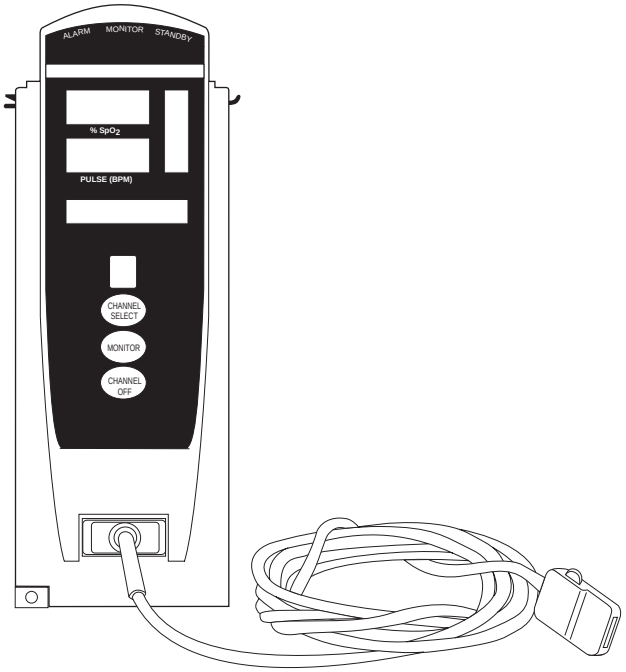
Directions for Use

SpO_2 Module, 8220 Series



SpO_2 MODULE
MODEL 8220

ALARIS Medical Systems, Inc.

Medley™ Medication Safety System

GENERAL CONTACT INFORMATION

Customer Advocacy - North America

Clinical and technical feedback.

Phone: (800) 854-7128, Ext. 7812
E-Mail: CustomerFeedback@alarismed.com

Technical Support - North America

Maintenance and service information support; troubleshooting.

United States:
Phone:
(858) 458-6003
(800) 854-7128, Ext. 6003

Canada:
Phone:
Eastern: (800) 908-9918
Western: (800) 908-9919

Customer Care - North America

Instrument return, service assistance, and order placement.

United States:
Phone:
(800) 482-4822

Canada:
Phone:
(800) 387-8309

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INTRODUCTION

About the SpO_2 Module

The Medley™ SpO_2 Module is indicated for continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate measured by an SpO_2 sensor. The SpO_2 Module and accessories are indicated for use with adult, pediatric and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals and hospital-type facilities.

Only 1 SpO_2 Module can be connected to a Medley™ Point-of-Care Unit.

NOTE: The Medley™ Point-of-Care Unit was formerly known as the Medley™ Programming Module.

The SpO_2 Module uses a wide variety of Masimo® PC patient cables and Masimo® LNOP® series sensors. The Masimo® cables and sensors are designed for use with the Model 8220 SpO_2 Module. For specific directions for use, refer to the cable and sensor packaging.

Contraindications: The SpO_2 Module with Masimo® PC patient cables and Masimo® LNOP® series sensors are contraindicated for use as an apnea monitor.

This document provides directions for use for the Medley™ SpO_2 Module, Model 8220.

WARNING

Read all instructions, for both the SpO_2 Module and Point-of-Care Unit, before using the Medley™ System.

Principle of Operation

The operation of the Medley™ SpO_2 Module is based on the principles of pulse oximetry. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry). The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).

Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation.

About the SpO_2 Module (Continued)

Principle of Operation (Continued)

The SpO_2 Module uses the Masimo® Signal Extraction Technology® (SET®) to decompose the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component. Its value is used to find the SpO_2 saturation in an empirically derived equation in the Masimo® SET® software. The values in the look-up table are based on human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia states during motion and nonmotion conditions.

Features and Definitions

Reference the “Alarms, Errors, Messages” chapter of the Medley™ Point-of-Care Unit Directions for Use (DFU) for the definitions of various alerts. Reference the Point-of-Care Unit DFU for system features and definitions.

% SpO_2 Alarm Limits	Upper and lower saturation alarm limits are displayed.
% SpO_2 Display	Functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO_2.
Fast SAT	When Fast SAT is enabled and there is 1 data point that is significantly different from a previous data point, averaging is disregarded and most recent data point is displayed. For example, if readings were 97%, 96%, 95% and 85%, displayed saturation level would be 85%.
Limit Mode	Displays either adult or neonatal monitoring mode.
PI	Perfusion Index (PI) is a scaled numeric value derived from magnitude of pulsations displayed on plethysmographic (pleth) waveform. It is calculated as a percentage of pulsatile signal to nonpulsatile signal. PI is used to find best perfused site for sensor placement (larger the PI, stronger the perfusion). Operating range is 0.02 to 20.0. Desired number is >1.00 or as large as possible.
Pleth Waveform	Plethysmographic (pleth) waveform is a graphic representation of changes in extremity blood volume during events of cardiac cycle.
Presilence	Alarms can be presilenced for 120 seconds. Presilence alarm can be cancelled before 120 seconds are complete.
Pulse Beat Volume	Can be configured to be off or to a volume level of 1, 2 or 3.

Features and Definitions (Continued)

Pulse Rate	Displayed in beats per minute (bpm).
Pulse Rate Alarm Limits	Upper and lower limits are displayed.
Saturation Averaging Time	Averaging time can be set to 2, 4, 8, 10, 12, 14 or 16 seconds.
Sensitivity Mode	Sensitivity mode, normal or maximum, of current monitoring configuration is displayed in options mode. Normal setting is used for normal patient monitoring purposes. Maximum setting is used for improved low perfusion performance.
SET® Technology	Signal Extraction Technology® (SET®) uses adaptive filters to separate arterial signal from nonarterial noise. SET® provides for accurate readings under extreme conditions; such as, low perfusion and motion.
Signal I.Q.™ Feature	A visual indication of pulsation at sensor site. Vertical bar height indicates quality of measured signal. Signal I.Q.™ feature is related to proper sensor application, adequate arterial signal and intensity of motion. Use Signal I.Q.™ feature to verify optimal sensor placement.
Trend Data	A tabular display of %SpO_2 and Pulse Rate. Display shows alarm conditions for time period displayed and average, high and low values. Data is stored for 24 hours.

Symbols

Attention: Refer to accompanying documentation.

Canadian and U.S. Certification Mark: Products bearing this mark have been tested and certified in accordance with applicable U.S. and Canadian electrical safety and performance standards (CSA C22.2 No. 601.1, UL 60601–1).

Consult operating instructions.

Electrical Shock Protection Rating: Type BF applied part.

IPX1

Protection against fluid ingress: Drip Proof

IUI Connector: Inter-Unit Interface connector used to establish power and communications between Point-of-Care Unit and attached modules.

Manufacturing Date: Number adjacent to symbol indicates month and year of manufacture.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on order of a physician.

Do not use if package is damaged.

Warnings and Cautions

℞ Only

Warnings and Cautions provided throughout this Directions for Use (DFU) provide information needed to safely and effectively use the Medley™ SpO_2 Module and accessories. Medley™ System Warnings and Cautions, and definitions, are covered in the Point-of-Care Unit DFU.

General

WARNINGS

- The SpO_2 Module is **NOT to be used as an apnea monitor**.
- **Pulse oximetry readings and pulse signal** can be affected by certain ambient conditions, sensor application errors and certain patient conditions.
- The SpO_2 Module is **intended only as an adjunct in patient assessment**. It must be used in conjunction with clinical signs and symptoms.
- The SpO_2 Module should be considered an **early warning device**. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-Oximeter to completely understand the patient's condition.
- **Interfering Substances:** Carboxyhemoglobin and methemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
- Do not use the SpO_2 Module or sensors during Magnetic Resonance Imaging (**MRI**).
- The SpO_2 Module is **not rated for defibrillation use**. Disconnect the sensor from the patient or patient cable from the module prior to defibrillation.
- If an alarm condition on the SpO_2 Module occurs **while the audio alarm is silenced**, the only alarm indications will be visual displays and symbols related to the alarm condition.

Warnings and Cautions (Continued)

General (Continued)

WARNINGS

- **Check alarm limits** each time the SpO_2 Module is used, to ensure they are appropriate for the patient being monitored.
- Do not lift the SpO_2 Module by the cable or power cord because the cable or **cord could disconnect from the instrument**, causing it to drop on the patient. Do not place the SpO_2 Module in any position that might cause it to fall on the patient.

CAUTION

To ensure **Electromagnetic Compliance** Integrity, accessories including external communication systems (hospital data communication equipment and/or Nurse call systems) must be certified to applicable standards:

- IEC 60601-1 (Electromedical Equipment) or
- IEC 950 (Data Processing Equipment)

> **NOTE:** Nurse Call systems must be certified to UL 1069 (Hospital Signaling and Nurse Call Equipment) or comply with requirements specified in IEC 60601-1.

Compliance with the electromagnetic compatibility standard (IEC 60601-1-2) is a function of all interconnected equipment including cabling; as such, it is the responsibility of the user to ensure external equipment complies with the applicable EMC standards. Failure to verify such external equipment meets applicable EMC standards may result in degraded electromagnetic compatibility.

Sensors and Cables

WARNINGS

- **Inspect the SpO_2 sensor site regularly** to ensure correct sensor positioning, application and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient profile (such as, neonates) and method of application. Refer to the sensor instructions for additional information.

Sensors and Cables (Continued)

WARNINGS

- **Carefully route patient cabling** to reduce the possibility of patient entanglement or strangulation.
- Before use, **read sensor directions** for use, including all warnings, cautions and instructions.
- **Use only approved Masimo® LNOP® sensors and PC Series patient cables**. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.
- Do not use a sensor, cable, connector or SpO_2 Module that **appears damaged**. Do not use a sensor with **exposed optical components**. **Do not immerse or wet** the sensor or cable. Clean per manufacturer's instructions (refer to LNOP® sensors instructions for use).
- The **sensor disconnect error message** and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor and/or pulse oximetry cable.

Measurements

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and then check the SpO_2 Module to ensure it is functioning properly.

An inaccurate measurement may be caused by:

- Incorrect sensor application or use.
- Significant levels of dysfunctional hemoglobins; such as, carboxyhemoglobin or methemoglobin.
- Intravascular dyes such as, indocyanine green or methylene blue.

- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp or direct sunlight.

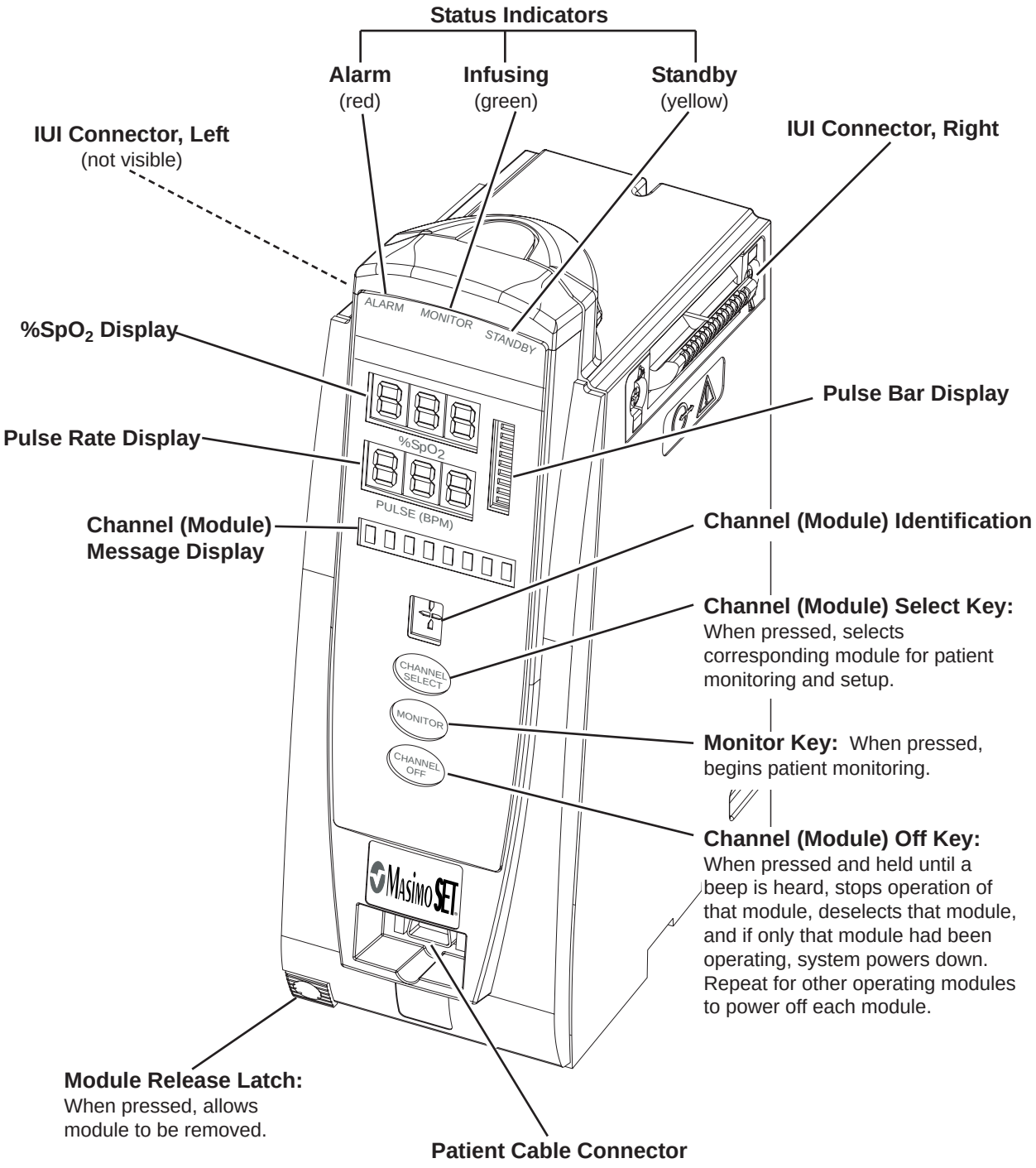
> **NOTE:** Exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material.

- Prolonged and/or excessive patient movement.
- Venous pulsations.
- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- Nail aberrations, nail polish, fungus, etc. Remove nail polish and/or move sensor to an unaffected site.
- Placement is too close to electrosurgery equipment.
- Defibrillation.

The loss of a pulse signal can occur in any of the following situations:

- Sensor is too tight.
- Exposure to excessive illumination; such as, a surgical lamp (especially one with a xenon light source), bilirubin lamp, fluorescent light, infrared heating lamp or direct sunlight.
- Sensor placed on an extremity with a blood pressure cuff, arterial catheter, intravascular line or other causes of insufficient perfusion.
- Patient has hypotension, severe vasoconstriction, severe anemia or hypothermia, is in cardiac arrest or is in shock.
- There is arterial occlusion proximal to sensor.
- Placement is too close to electrosurgery equipment.

Operating Features, Controls and Indicators



Installation

Instruments are tested and calibrated before they are packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the instrument in use.

Prior to placing the Medley™ System in use: Perform check-in procedure per Medley™ Maintenance Software/User Manual (Model 8970C, or later).

Attaching and Detaching Modules

Reference the Medley™ Point-of-Care Unit DFU.

Displays

The displays illustrated throughout this document are for illustration purposes only. The display content will vary, depending on configuration settings and other variables.

Main Display

Reference the Medley™ Point-of-Care Unit DFU.

Start-Up

Reference the Medley™ Point-of-Care Unit DFU for the following procedures:

Powering On System
Responding to Maintenance Reminder
Selecting New Patient and Profile Options
Entering Patient ID
Modifying Patient ID

General Setup and Use

1. Attach Masimo® patient cable to SpO_2 Module. Ensure secure connection and patient cable is not twisted, sliced or frayed.
2. Attach Masimo® LNOP® sensors to Masimo® patient cable. Refer to sensor's directions for use for detailed instructions.
3. Ensure sensor's red LED is on.
4. Attach sensor to patient. Refer to sensor's directions for use for detailed instructions.
5. Verify high and low alarm rates for SpO_2 and pulse rate are correct for patient by selecting **CHANNEL SELECT** key.

> **NOTES:**
>
> - **SEARCHING** may appear in Channel Message Display until SpO_2 and pulse readings have stabilized (approximately 15 seconds).
> - If sensor is not attached to a site after powering up, module will display **SENSOR OFF**. If sensor is not attached during message display, module will go into sleep mode. To begin monitoring once module is in this mode, press **MONITOR** key.

6. Monitor patient.
7. After patient monitoring is complete, remove sensor from patient according to hospital protocol.
8. Turn off SpO_2 Module by pressing and holding **CHANNEL OFF** key for 1 second.

> **NOTE:** Module will initiate power down when **CHANNEL OFF** key is released.

WARNING

Use only approved Masimo® LNOP® sensors and PC Series patient cables. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.

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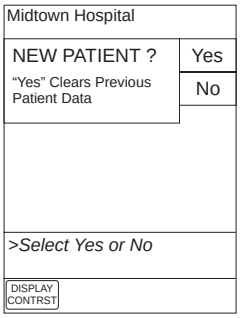
Monitoring Mode

Navigating Main Display

1. Attach SpO_2 Module to Point-of-Care Unit.
2. Power on system by pressing **SYSTEM ON** key on Point-of-Care Unit.
   - **NEW PATIENT?** screen appears.

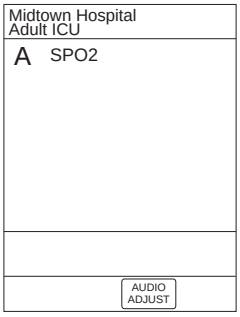


3. To clear previous SpO_2 trend data, press **Yes** soft key.

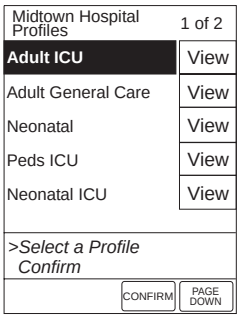
   OR

   To retain previous SpO_2 trend data, press **No** soft key.
   - Main Display appears.

   OR



   If Guardrails® Safety Software is enabled, profiles screen appears.



> **NOTE:** When Guardrails® Safety Software is enabled:
> - If **Yes** is selected, a prompt to confirm last profile selected appears.
> - If **No** is selected, a prompt to choose a profile appears.

4. Attach patient cable and sensor as described in "Getting Started" chapter, "General Setup and Use" section.

Powering Off

Reference the Medley™ Point-of-Care Unit DFU for the following procedures:

Powering Off System

Powering Off Module

Reviewing Serial Number

Reference the Medley™ Point-of-Care Unit DFU.

Reviewing Software Version

Reference the Medley™ Point-of-Care Unit DFU.

ALARMS AND MESSAGES

To enhance safety and ease of operation, the Medley™ System provides a full range of audio and visual alarms, errors, and messages.

Definitions

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

Audio Characteristics

Reference the Medley™ Point-of-Care Unit DFU.

WARNING

If an alarm condition on the SpO_2 Module occurs while the audio alarm is silenced, the only alarm indication will be a visual display and symbol related to the alarm condition.

Alarms

Alarm	Meaning	Response
Bad Sensor	Broken, unknown or nonsystem sensor or patient cable attached.	Check sensor and patient cable. Confirm correct sensor and patient cable are chosen. Reference “Appendix” chapter, “Accessories” section for a list of sensors designed for use with this module.
Check Sensor - Electrical or Optical Interference	External interference on sensor.	Check sensor. Identify source of external interference if other than sensor.
Check Sensor - Light	Light interference on sensor.	Check sensor. Remove or reduce lighting. Cover or reposition sensor.
Check Sensor - Low Perfusion	Patient’s low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Low Signal I.Q.	Low signal quality being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.

Alarms (Continued)

Alarm	Meaning	Response
High Pulse Rate Alarm	High pulse rate alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
High SpO_2 Alarm	High SpO_2 alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
Low Pulse Rate Alarm	Low pulse rate alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
Low SpO_2 Alarm	Low SpO_2 alarm limit has been exceeded.	Access patient's condition. Confirm correct alarm limit values are selected.
No Sensor	Sensor not properly attached to patient cable or patient cable not properly attached to SpO_2 Module.	Attach sensor to patient cable or attach patient cable to SpO_2 Module.
No Signal	Failure to find a patient signal after 30 seconds of searching.	Check sensor. Confirm correct sensor placement.
Remove Module (Max=1)	More than 1 SpO_2 Module attached.	Remove additional SpO_2 Module.
Sensor Off	Sensor not properly attached to patient.	Reattach sensor to patient.

Messages

Message	Meaning	Response
Check Sensor - Low Perfusion	Patient's low perfusion has inhibited monitoring.	Check sensor. Move sensor to a better perfused site.
Check Sensor - Low Signal I.Q.	Low signal quality being measured.	Check sensor. Confirm correct sensor placement. Move sensor to a better perfused site.

The Medley™ System Technical Service Manual is available from ALARIS Medical Systems. It includes routine service schedules, interconnect diagrams, component parts lists and descriptions, test procedures, and other technical information, to assist qualified service personnel in repair and maintenance of the instrument's repairable components. Maintenance procedures are intended to be performed only by qualified personnel, using the service manual and Medley™ Maintenance Software.

Specifications

Accuracy and Motion Tolerance:

Pulse Rate:

Low Perfusion[1]	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±3 digits
Motion[2, 3]	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±5 digits
No Motion[4]	
Adults, Pediatrics, Neonates	25 - 240 bpm, ±3 digits
Resolution	1 bpm

Saturation:

Low Perfusion[1]	
Adults, Pediatrics	70 - 100%, ±2 digits
Neonate	70 - 100%, ±3 digits
Motion[2, 3]	
Adults, Pediatrics, Neonate	70 - 100%, ±3 digits
No Motion[4]	
Adults, Pediatrics	70 - 100%, ±2 digits
Neonates	70 - 100%, ±3 digits
Resolution	1% SpO_2

1 Masimo® Board performance has been validated for low perfusion accuracy in bench–top testing against a BIO-TEK simulator and a Masimo® simulator. Refer to service manual for more information.

2 Masimo® Board performance has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a nonrepetitive range of 70-100% SpO_2 against a laboratory co–oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

3 Masimo® Board performance with Masimo® LNOP® Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates, while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co–oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 Masimo® Board performance has been validated for no-motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies, in the range of 70-100% SpO_2 against a laboratory co–oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Specifications (Continued)

Alarms: Audible and visual alarms for high and low saturation and pulse rate, sensor condition, system failure and low battery conditions.

Alarm Limits:	**Low**	**High**
Pulse Rate:	30-239 bpm	31-240 bpm
SpO_2	20-99%	21-100%

Dimensions: 3.3"W x 8.9"H x 5.5"D
(8.4cm W x 22.6cm H x 14cm D)

Display Update Period: Approximately 1 second.

Electrical Classification: Class 1, Internally Powered Equipment, Type BF

Environmental Conditions:	Operating	Storage/Transport
Temperature Range:	41 to 104°F (5 to 40°C)	-4 to 140°F (-20 to 60°C)
Relative Humidity:	20 to 90% Noncondensing	5 to 85% Noncondensing
Atmospheric Pressure:	525 to 4560 mmHg (700 to 6080 hPa)	375 to 760 mmHg (500 to 1013 hPa)

Fluid Ingress Protection: IPX1, Drip Proof

Measurement Range:

Perfusion	0.02 to 20%
Pulse Rate	25 to 240 bpm
SpO_2	1 to 100%

Mode of Operation: Continuous

Pulse Amplitude Display: Proportional to height of I.Q. signal.

Sensor: Emitted light wavelength range is within 500 nm to 1000 nm. Output power does not exceed 1 mw.

Weight: 2 lbs (0.91 kg)

NOTE: Compliance to Standards

The Medley™ Medication Safety System has been assessed and complies with the following standards: UL 60601–1; CSA C22.2 No. 601.1, including A1 and A2; IEC 60601–1–2.

Configurable Settings

If the configuration settings need to be changed from the "Factory Default" settings, reference the applicable Technical Service Manual or contact ALARIS Medical Systems Technical Support for technical, troubleshooting, and preventive maintenance information.

NOTE: With the Profiles feature enabled, the settings are configured independently for each profile. A hospital-defined, best-practice data set must be uploaded to enable the Profiles feature. Date and Time is a system setting and is the same in all profiles.

System Settings

Reference the Medley™ Point-of-Care Unit Directions for Use (DFU).

SpO_2 Module Settings

Feature	Default Setting	Options
Limit Mode	Adult	Adult, Neonatal
Pulse Beep Volume	1	1, 2, 3, Off
Pulse Rate Alarm Limit, High	Adult Mode: 120 bpm Neonatal Mode: 200 bpm	31 - 240 bpm
Pulse Rate Alarm Limit, Low	Adult Mode: 50 bpm Neonatal Mode: 100 bpm	30 - 239 bpm
SpO_2 Alarm Limit, High	Adult: Off Neonatal: 95%	21 - 100%, Off
SpO_2 Alarm Limit, Low	Adult: 90% Neonatal: 80%	20 - 99%
Saturation Averaging Time (display update period)	8 seconds	2, 4, 8, 10, 12, 14, 16 seconds
Sensitivity Mode	Normal	Normal, Maximum

Cleaning

Reference the Medley™ Point-of-Care Unit DFU for module cleaning instructions. For sensor/cable cleaning, reference the instructions provided with the sensor/cable.

Inspection Requirements

To ensure the system remains in good operating condition, both regular and preventive maintenance inspections are required. Reference the Medley™ Maintenance Software/User Manual (Model 8970C, or later) for detailed instructions.

WARNING

Failure to perform these inspections may result in improper instrument operation.

CAUTION

Regular and preventive maintenance inspections should only be performed by qualified service personnel.

REGULAR INSPECTIONS

PROCEDURE	FREQUENCY
CLEANING	As required
INSPECT FOR DAMAGE:	
Case	Each usage
IUI connector	Each usage
Keypad	Each usage
START-UP	Each usage

PREVENTIVE MAINTENANCE INSPECTIONS

PROCEDURE	FREQUENCY
Alarm Test	12 months
Channel Identification Test	12 months
Channel Operation Test	12 months
Functional test	12 months
Keypad Test	12 months
Patient Lead Electrical Leakage Test	12 months

Service Information

Reference the Medley™ Point-of-Care Unit DFU.

WARRANTY

ALARIS Medical Systems, Inc., (hereinafter referred to as "ALARIS Medical Systems") warrants that:

A. Each new ALARIS Medical Systems® Medley™ SpO_2 Module is free from defects in material and workmanship under normal use and service for a period of one (1) year from the date of delivery by ALARIS Medical Systems to the original purchaser.

B. Each new accessory is free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by ALARIS Medical Systems to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the relevant account representative to determine the appropriate repair facility. Except as provided otherwise in this warranty, repair or replacement will be carried out at ALARIS Medical Systems' expense. The product requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall ALARIS Medical Systems be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any ALARIS Medical Systems® Product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and ALARIS Medical Systems shall not be responsible for, any loss or damage arising in connection with the purchase or use of any ALARIS Medical Systems® Product which has been:

(a) repaired by anyone other than an authorized ALARIS Medical Systems Service Representative;

(b) altered in any way so as to affect, in ALARIS Medical Systems' judgment, the product's stability or reliability;

(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, effaced or removed;

or

(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by ALARIS Medical Systems.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of ALARIS Medical Systems, and ALARIS Medical Systems does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of ALARIS Medical Systems any other liability in connection with the sale or use of ALARIS Medical Systems® Products.

ALARIS MEDICAL SYSTEMS DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

See packing inserts for international warranty, if applicable.

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Accessories

Masimo® LNOP® Sensors

When selecting a sensor, consider the patient's weight, the adequacy of perfusion, the available sensor sites and the duration of monitoring. For more sensor information, reference the table at the end of this section or contact a Masimo sales representative. Use only Masimo® SET® sensors. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

Clean and remove any substances (such as, nail polish) from the application site. Periodically check to ensure that the sensor remains properly positioned on the patient.

High ambient light sources (such as, surgical lights, especially those with a xenon light source, bilirubin lamps, fluorescent light, infrared heating lamps and direct sunlight) can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied and cover the sensor site with opaque material.

Reattaching a Sensor:

- Masimo® LNOP® single-use sensors may be reattached to the same patient if emitter and detector windows are clear and adhesive still adheres to skin.
- Adhesive can be partially rejuvenated by wiping it with an alcohol wipe and allowing it to thoroughly air dry prior to reattaching it to the patient.

NOTE: If the sensor fails to track the pulse consistently, it may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.

WARNINGS

- Before use, **read sensor directions** for use, including all warnings, cautions and instructions.
- **Use only approved Masimo® LNOP® sensors and PC Series patient cables**. Use of sensors, transducers, cables and accessories other than those specified may cause improper SpO_2 Module performance resulting in inaccurate readings, increased emission and/or decreased immunity, and degraded electromagnetic compatibility performance of the SpO_2 Module.
- **Inspect the SpO_2 sensor site regularly** to ensure correct sensor positioning, application and site integrity. Tissue damage could occur over prolonged time periods, depending on the patient profile (such as, neonates) and method of application. Refer to the sensor instructions for additional information.
- **Do not use** a sensor that appears damaged. **Do not use** a sensor with exposed optical components.

CAUTIONS

- Failure to **cover the sensor site with opaque material** in high ambient light conditions may result in inaccurate measurements.
- **Before bathing** the patient, completely disconnect the patient from the SpO_2 Module and sensor.

Accessories (Continued)

Masimo® LNOP® Sensors (Continued)

Masimo® Single-Patient SpO_2 Adhesive Sensor	Model	Patient Size	Site Inspection Interval
LNOP®-Adt	1001	>30 kg	Check and move sensor to a new site every 8 hours, as necessary.
LNOP®-Neo	1002	<10 kg	Not Applicable
LNOP®-NeoPt	1003	<1 kg	Not Applicable
LNOP®-Pdt	1025	>10 or <40 kg	Not Applicable

Masimo® Reusable SpO_2 Sensor	Part Number	Patient Size	Site Inspection Interval
LNOP®-DCI	1269	30 kg	Check and move sensor to a new site every 4 hours.
LNOP®-DCIP	1276	10 or <50 kg	Not Applicable
LNOP®-EAR, Ear Reusable Sensor w/Ear Hanger	1399	>30 kg	Not Applicable
LNOP®-Y1, Multisite Reusable Sensor	1544	1 kg	Not Applicable

Masimo® SET® Patient Cables

Reusable patient cables of various lengths are available. All cables that display the Masimo® SET® logo are designed to work with any Masimo® LNOP® sensor and with any SpO_2 Module displaying the Masimo® SET® logo.

WARNINGS

- **Carefully route patient cabling** to reduce the possibility of patient entanglement or strangulation.
- Do not use a cable that **appears damaged**.
- Do not lift the SpO_2 Module by the cable because the **cable could disconnect from the instrument**, causing it to drop on the patient.

ALARIS®
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Patents, Patente, 專利:
AT – 693,662; 703,178; 728,366; 730,203. **TW** – NI-107,963. **US** – 5,601,445; 5,713,856; 5,836,910; 5,941,846.
Masimo® – 5,482,036; 5,490,505; 5,632,272; 5,685,299; 5,758,644; 5,769,785; 6,002,952; 6,036,642; 6,067,462; 6,157,850; 6,206,830; and international equivalents.
Other Patents Pending

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